

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : HOFFMANN et al.
Serial No. : 10/533,926 (U.S. Patent Application Publication 2006-0013864)
Filing Date : 17 October 2003 (PCT filing date)
For : TRANSMUCOSAL PHARMACEUTICAL ADMINISTRATION FORM
Examiner : ORWIG, Kevin S.
Art Unit : 1611

745 Fifth Avenue
New York, NY 10151

PETITION UNDER 37 C.F.R. § 1.181
(Prematurity of final rejection - MPEP § 706.07(c))

Mail Stop: **Petitions (Group Director 1610 – George Elliott)**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please accept this petition against the holding of finality of the Office Action dated 23 January 2009. The Commissioner is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

ACTION REQUESTED

The applicants request withdrawal of the final rejection as new grounds of rejections were made by the Examiner which were not necessitated by the applicants' amendments.

STATEMENT OF FACTS

The applicants received a first Office Action on the merits dated **28 May 2008** which include an objection to claims 1-11, a rejection of claims 5-10 under 35 U.S.C. 112, first paragraph for lack of written description, a rejection of claim 6 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement, a rejection of claims 1-11 under 35 USC 112, second paragraph and the following obviousness rejections:

- (1) Claims 1-5 over Zhang et al. (U.S. Patent 6,264,981 – “**Zhang**”) **in view of** Patel et al. (U.S. Patent 6,248,363 – “**Patel**”); Weete et al. (U.S. Patent 5,703,255 – “**Weete**”), *Steadman’s Medical Dictionary* (Lippincott & Wilkins, 2000; accessed online 5/13/2008 – “**Steadman**”); and by Raisch et al. (Ann. Pharmacother., 2002 February; 36(2): 312-321 – “**Raisch**”).
- (2) Claims 1, 6 and 7 over Zhang et al. (U.S. Patent 6,264,981 – “**Zhang**”) **in view of** Patel et al. (U.S. Patent 6,248,363 – “**Patel**” and Shen et al. (U.S. Patent 6,255,490 – “**Shen**”).
- (3) Claims 1 and 8 over Zhang et al. (U.S. Patent 6,264,981 – “**Zhang**”) **in view of** Patel et al. (U.S. Patent 6,248,363 – “**Patel**” and Myer et al. (U.S. Patent 5,977,144 – “**Myer**”).
- (4) Claims 1 and 9 over Zhang et al. (U.S. Patent 6,264,981 – “**Zhang**”) **in view of** Patel et al. (U.S. Patent 6,248,363 – “**Patel**” and Cary (U.S. Patent 6,197,827).
- (5) Claims 1 and 10 over Zhang et al. (U.S. Patent 6,264,981 – “**Zhang**”) **in view of** Patel et al. (U.S. Patent 6,248,363 – “**Patel**” and Plotnikoff et al. (U.S. Patent 3,706,831 – “**Plotnikoff**”).
- (6) Claims 1 and 11 over Zhang et al. (U.S. Patent 6,264,981 – “**Zhang**”) **in view of** Patel et al. (U.S. Patent 6,248,363 – “**Patel**” and Serra et al. (*Eur. J. Pharmacol.* 2001 November; 430(2-3): 369-371 – “**Serra**”).

The applicants filed a response on **28 October 2008** which addressed the objections and rejections made in the first Office Action. Summarizing the amendments made in this response, the elements of original claims 2, 7, 9, 10 and 11 were inserted into claim 1. Claims 5, 6 and 8 were cancelled. New claims 12 and 13 have been added which split a) and b) from claim 1 into separate dependent claims. Also, the applicants amended the claims to refer to the narrower embodiment of ---salts--- in lieu of “derivative”.

The final rejection mailed on **23 January 2009** withdrew all previous rejections made in the Office Action of 28 July 2008 and introduced a **new 35 U.S.C. 112, first paragraph rejection based on new matter, a new 35 U.S.C. 112, second paragraph rejection and new 35 U.S.C. 103 rejections** of claim 13 over Zhang in view of Patel, Weete and Majeti.

REASONS THAT CURRENT REJECTION IS A NEW GROUND FOR REJECTION

The applicants' amendment did not necessitate the new grounds of rejection under 35 U.S.C. 103 because the result of the applicants' claim amendments served to narrow the scope of the claims under consideration and did not introduce new limitations which were not previously disclosed in the claims, i.e. the scope of the claims under examination were disclosed in the originally filed claims.

Moreover, the guidelines for conducting a search are recited in MPEP 904.03 which states in part:

“It is a prerequisite to a speedy and just determination of the issues involved in the examination of an application that a careful and comprehensive search, commensurate with the limitations appearing in the most detailed claims in the case, be made in preparing the first action on the merits so that the second action on the merits can be made final or the application allowed with no further searching other than to update the original search. It is normally not enough that references be selected to meet only the terms of the claims alone, especially if only broad claims are presented; *but the search should, insofar as possible, also cover all subject matter which the examiner reasonably anticipates might be incorporated into applicant's amendment.* Applicants can facilitate a complete search by including, at the time of filing, claims varying from the broadest to which they believe they are entitled to the most detailed that they would be willing to accept.

In doing a complete search, the examiner should find and cite references that, while not needed for treating the claims, would be useful for forestalling the presentation of claims to other subject matter regarded by applicant as his or her invention, by showing that this other subject matter is old or obvious.” (emphasis added)

With regard to the rejections based on use of the phrase ---salts thereof---, clearly salt forms are a type of derivative and which is well known to those of ordinary skill in the pharmaceutical art and should have been anticipated as being a part of an amendment to the claim. (There is no basis for the rejection based on lack of written description as salt forms of pharmaceutical compounds have been well established in the art. Moreover, there was no basis

for lacking adequate metes and bounds as one of ordinary skill in the art would be able to determine whether an active agent was a salt form or not.)

In addition, the amendment to recite salt forms was not presented as a concession that the original rejection was proper, but a good faith effort to advance prosecution of the application.

Likewise, the rejection of claim 13 introduces a new reference previously not relied upon by the Examiner, i.e. the Majeti reference. As noted above, the elements of claim 13 were already present in original claim 1 and therefore should have been examined in the first Office Action on the merits and/or anticipated as a possible claim amendment.

For these reasons, the applicants respectfully request that the finality of the rejection be withdrawn.

CONCLUSION

In view of the remarks made above, it is believed that the finality of the rejection should be withdrawn. Favorable reconsideration is earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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